

**THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**KATHERINE CROCKETT,
Plaintiff,**

CIVIL ACTION

v.

**LUITPOLD PHARMACEUTICALS, INC.,
et al.,
Defendants.**

NO. 19-276

MEMORANDUM OPINION

Defendant Vifor Pharma Management, Ltd. (“Vifor Management”) moves to dismiss the Complaint brought against it by Plaintiff Katherine Crockett on the grounds that this Court lacks personal jurisdiction over Vifor Management.

I. FACTS

The facts in this case have already been recounted at length. *See Crockett v. Luitpold Pharms., Inc.*, 2020 WL 433367 (E.D. Pa. Jan. 28, 2020). In brief, this is a product liability action brought by Plaintiff, a Pennsylvania resident, after she took Injectafer, an FDA-approved prescription injection for the treatment of iron deficiency anemia. Injectafer is one of several products available for intravenous iron but is the only such product available in the United States formulated with the unique ferric carboxymaltose (“FCM”) compound. Plaintiff alleges that she developed severe hypophosphatemia after taking Injectafer as prescribed.

Injectafer is manufactured, distributed, and sold in the United States by Defendant American Regent, Inc. (“American Regent”)¹ and since 2017 has been marketed in the United States by Defendant Daiichi Sankyo, Inc. (“DSI”).

¹ Effective January 1, 2019, Luitpold Pharmaceuticals, Inc. merged with American Regent, Inc.

In addition to American Regent and DSI, the Third Amended Complaint names as Defendants Vifor Management and several other Vifor entities—Vifor Pharma, Ltd., Vifor Pharma Participations, Ltd., Vifor (International) AG, and Relypsa, Inc. (together, “Vifor Defendants”). The Vifor Defendants develop, manufacture, and sell FCM in Europe as Ferinject.

Plaintiff alleges that Vifor Management—the sole Defendant that has brought a motion premised on lack of personal jurisdiction—is “headquartered in Switzerland.” The rest of her allegations pertain to the Vifor Defendants as a group, claiming they:

- “[A]re in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into commerce ferric carboxymaltose, or its European brand bioequivalent, Ferinject.”
- “[B]y and through Vifor International, are engaged in a licensing deal with Luitpold that permits Luitpold to design, manufacture, market, supply, promote, label, distribute, and sell Injectafer in the United States.”
- “[L]icensed that ferric carboxymaltose design to Luitpold, which in turn designed, manufactured, marketed, supplied, distributed, and sold the bioequivalent Injectafer product to the United States market.”
- “[D]irectly participated in the registration and clinical trials, marketing, promotion and marketing sales organization, safety reporting, adverse events arising from clinical trials, and pharmacovigilance obligations for Injectafer, which—either in whole or in substantial part—were conducted or managed in Luitpold’s Norristown, PA location” pursuant to the Vifor International-Luitpold licensing agreement.
- “[A]re engaged in the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer, which—either in whole or in substantial part—were conducted or managed in Luitpold’s Norristown, PA location.”

As discussed below, Vifor Management disputes many of these allegations through a sworn affidavit, the Goulburn Declaration (“Goulburn Decl.”). Plaintiff has not provided an opposing declaration but has attached eleven exhibits to her opposition brief as evidence in support of her argument that there is jurisdiction over Vifor Management in Pennsylvania.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(2) allows this Court to dismiss a complaint for “lack of personal jurisdiction.” Fed. R. Civ. P. 12(b)(2). To survive a motion to dismiss for lack of personal jurisdiction, “the plaintiff bears the burden of establishing personal jurisdiction.” *O’Connor v. Sandy Lane Hotel, Co.*, 496 F.3d 312, 316 (3d Cir. 2007). “[W]hen the court does not hold an evidentiary hearing on the motion to dismiss, the plaintiff need only establish a prima facie case of personal jurisdiction and the plaintiff is entitled to have its allegations taken as true and all factual disputes drawn in its favor.” *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004); *Carteret Sav. Bank, F.A. v. Shushan*, 954 F.2d 141, 142 n.1 (3d Cir. 1992).² If the plaintiff meets her burden, then the burden shifts back to the defendant to present a compelling case that personal jurisdiction is unreasonable. *Carteret*, 954 F.2d 141-42 (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985)).

“A Rule 12(b)(2) motion . . . is inherently a matter which requires resolution of factual issues outside the pleadings, i.e. whether in personam jurisdiction actually lies.” *Time Share Vacation Club v. Atlantic Resorts, Ltd.*, 735 F.2d 61, 66 n.9 (3d Cir. 1984). Thus,

once the defense has been raised, then the plaintiff must sustain its burden of proof in establishing jurisdictional facts through sworn affidavits or other competent evidence. [A]t no point may a plaintiff rely on the bare pleadings alone in order to withstand a defendant’s Rule 12(b)(2) motion to dismiss for lack of in personam jurisdiction. Once the motion is made, plaintiff must respond with actual proofs, not mere allegations.

Patterson v. FBI, 893 F.2d 595, 603-04 (3d Cir. 1990).

Personal jurisdiction over a non-resident defendant is proper only if permitted by

² “A district court . . . may require more than a prima facie showing of jurisdiction by holding a quasi-evidentiary hearing. . . .” C. Wright & A. Miller, *Federal Practice & Procedure* § 1067.6. “[I]f the Court conducts an evidentiary hearing, the plaintiff has the more substantial burden of proving that personal jurisdiction is proper by a preponderance of the evidence.” *Steinfeld v. EmPG Intern., LLC*, 97 F. Supp.3d 606, 611-12 (E.D. Pa. 2015) (internal quotations and citations omitted). The Court has reviewed the exhibits attached to their briefs by the parties and, having done so, does not find it necessary to hold an evidentiary hearing.

Pennsylvania's long-arm statute and the United States Constitution. *See Pennzoil Prods. Co. v. Colelli & Assocs., Inc.*, 149 F.3d 197, 200 (3d Cir. 1998). Pennsylvania's long-arm statute authorizes personal jurisdiction to the extent permitted by the Fourteenth Amendment of the Constitution. *See* Pa. C.S.A. § 5322(b); *Vetrotex Certainteed Corp. v. Consol. Fiber Glass Prods. Co.*, 75 F.3d 147, 150 (3d Cir. 1996). As a result, the personal jurisdiction inquiry merges into a single due process analysis under the Constitution. *O'Connor*, 496 F.3d at 316.

III. ANALYSIS

Defendant argues that because Vifor Management is a Swiss company with no substantial contacts in Pennsylvania, this Court has neither general nor specific jurisdiction, and the Complaint against it should be dismissed for lack of personal jurisdiction under Rule 12(b)(2).

Plaintiff does not respond to Defendant's argument that the Court lacks general jurisdiction here. "[I]ssues not briefed are deemed waived. Where a party makes no more than a single mention of the claim, the claim is consequently waived." *United States v. Healy*, 2013 WL 1624310, at *1 (M.D. Pa. Apr. 15, 2013) (citing *National R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n*, 342 F.3d 242 (3d Cir. 2003)). The issue of general jurisdiction is waived, and the Court turns to specific jurisdiction.

To establish specific jurisdiction, Plaintiff must show that a "defendant's suit-related conduct . . . create[s] a substantial connection with the forum State." *Walden v. Fiore*, 571 U.S. 277, 284 (2014). The Third Circuit has held that the specific jurisdiction inquiry has three parts: (1) the defendant must have "purposefully directed [its] activities at the forum," (2) the litigation must "arise out of or relate to at least one of those activities," and (3) "if the first two requirements have been met a court may consider whether the exercise of jurisdiction comports with fair play and substantial justice." *D'Jamoos ex rel. Estate of Weingeroff v. Pilatus Aircraft*

Ltd., 566 F.3d 94, 102 (3d Cir. 2009). The defendant must have engaged in “a deliberate targeting of the forum.” *O’Connor*, 496 F.3d at 317. Defendant argues that Plaintiff fails all three requirements.

On the first prong—purposeful availment—Plaintiff argues that Vifor Management designed a product that harmed someone in Pennsylvania—in this instance, the Plaintiff. As a preliminary matter, the Third Circuit has rejected a “stream of commerce” theory as a basis for exercising specific jurisdiction over a foreign defendant. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 780 (3d Cir. 2018). An allegation that a foreign party engaged in efforts “‘to exploit a national market’ that ‘necessarily included Pennsylvania’ [is] insufficient.” *Id.* (quoting *D’Jamoos*, 566 F.3d at 104). Specific jurisdiction may be asserted over a defendant that places its product into a stream of commerce only where “the defendant’s activities manifest an intention to submit to the power of a sovereign,” that is, “the defendant must purposefully avail[] itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.” *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881-82 (2011) (internal quotations omitted).

Plaintiff relies heavily on the allegation that a different Vifor entity³ entered into a licensing agreement with American Regent, which “sold the bioequivalent Injectafer product to the United States market.” This is far too attenuated to create personal jurisdiction in Pennsylvania. It is notable that Plaintiff’s opposition brief opens by saying “[t]he Vifor Group is a consortium of companies. . . .” An allegation regarding another Vifor entity is not the same as

³ Plaintiff does not dispute that Vifor Management is not a party to the licensing agreement. Under the agreement, a separate Vifor entity—Vifor (International) AG—manufactures FCM in Switzerland, which it then ships to American Regent in New York, which transports the FCM to sites in Ohio, where American Regent reconstitutes, packages, distributes, and sells it across the United States. Goulburn Decl. ¶ 15.

an allegation about Vifor Management. Moreover, regardless of which Vifor entity is being discussed, the allegation speaks to selling in “the United States,” not in Pennsylvania specifically, and a third-party licensing agreement does not show intent to distribute in Pennsylvania. *See Yohn v. Waco Equip. Co.*, 2003 WL 22844220, at *3 (E.D. Pa. Nov. 26, 2003) (third-party defendant’s distribution agreement suggested it was aware its products would be sold in the United States but did not reflect an intent to distribute in Pennsylvania). “Mere knowledge or awareness” that a product may end up in Pennsylvania is not sufficient for personal jurisdiction. *See Renner v. Lanard Toys*, 33 F.3d 277, 282 (3d Cir. 1994).⁴

Plaintiff next turns to Vifor Management’s “coordination” with the U.S. Defendants. Specifically, she argues that Vifor Management “purposefully availed” itself of the Pennsylvania forum because it “engag[ed] in tortious misconduct . . . in coordination with the U.S. Defendants within the Commonwealth.” But “a defendant’s relationship with a . . . third party, standing alone, is an insufficient basis for jurisdiction.” *See Walden v. Fiore*, 571 U.S. 277, 286 (2014). In *Nicastro*, the Supreme Court found that the facts showed no “regular course” of sales in New Jersey and noted there was “no ‘something more,’ such as special state-related design, advertising, advice, marketing, or anything else” to warrant specific jurisdiction. 564 U.S. at 889 (Breyer, J., concurring). Plaintiff hangs her hat on the “something more” argument—suggesting “something more” exists here because of Vifor Management’s alleged cooperation with the U.S. Defendants—for example, by alleging the Vifor entities participated in “the registration and

⁴ Plaintiff’s reliance upon *Bristol-Meyers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017) (“*BMS*”), to argue that in-state injury creates jurisdiction over a foreign defendant is misplaced. There, the Supreme Court held that a California court lacked personal jurisdiction over claims brought by non-California plaintiffs against BMS even though BMS had contracted with a California company “to distribute [the drug] nationally.” *Id.* at 1783. Personal jurisdiction as to the California plaintiffs’ claims was not at issue because BMS sold nearly 187 million pills in California. *Id.* at 1778. By contrast, Vifor Management does not sell Injectafer in Pennsylvania; Plaintiff’s allegation that another Vifor entity contracted with American Regent to sell Injectafer in Pennsylvania is not analogous to the California plaintiffs in *BMS*.

clinical trials, marketing, promotion and marketing sales organization, safety reporting, adverse events arising from clinical trials, and pharmacovigilance obligations for Injectafer . . . in Luitpold’s Norristown, PA location.” Plaintiff’s argument that co-operation of a party who does no business in Pennsylvania with a third party engaged in business in Pennsylvania provides a basis for the exercise of specific jurisdiction over the first party is, as discussed *infra*, is unavailing. Further, Vifor Management’s affidavit disputes that it had any direct engagement , in the manufacture, advertisement, supply, promotion, sale, distribution, or study of Injectafer in Pennsylvania or anywhere else in the United States.⁵ *See* Goulburn Decl. ¶¶ 10-26.

To the extent Plaintiff seeks to impute American Regent and DSI’s Pennsylvania contacts and actions to Vifor Management, she has not cited any case law for doing so—particularly in the context of separate corporate entities. Indeed, this argument is routinely rejected as a basis for personal jurisdiction even in the closer parent-subsidary context. *See Kehm Oil Co. v. Texaco, Inc.*, 537 F.3d 290, 301 (3d Cir. 2008) (“The mere fact that a subsidiary company does business within a state does not confer jurisdiction over its nonresident parent.” (quoting *Escude Cruz v. Ortho Pharm. Corp.*, 619 F.2d 902, 905 (1st Cir. 1980))); *see also Arch v. Am. Tobacco Co.*, 984 F. Supp. 830, 838 (E.D. Pa. 1997) (refusing to impute an in-state entity’s contacts to a foreign parent company under the alter ego theory because there was no evidence of parent’s “undue domination and control”). Plaintiff conceded at oral argument that she is not pursuing an alter ego theory.

⁵ Additionally, Plaintiff’s reliance on two Superior Court decisions to show “something more” under *Nicastro* is unavailing. In *Hammons v. Ethicon*, 190 A.3d 1248 (Pa. Super. 2018), the court held that there was personal jurisdiction over Ethicon based on its own conduct directed at Pennsylvania. *See id.* at 1263-64 (finding Ethicon “supervised the design and manufacturing process of pelvic mesh in Pennsylvania” and “worked closely with an Allentown, Pennsylvania physician . . . developing” the medical device). There is no evidence of such conduct here. In *Vaughan v. Olympus Am., Inc.*, 208 A.3d 66, 74 (Pa. Super. 2019), the court attributed an in-state subsidiary’s conduct to its foreign parent because the subsidiary admitted it was the parent’s agent for “FDA-related conduct in Pennsylvania.” Here, there is no allegation or evidence that the U.S. Defendants were Vifor Management’s agents in Pennsylvania.

In short, Plaintiff has failed to meet her burden of establishing specific jurisdiction. *See Patterson*, 893 F.2d at 603-04 (noting that “once the [jurisdictional] defense has been raised, then the plaintiff must sustain [her] burden of proof in establishing jurisdictional facts through sworn affidavits or other competent evidence”). At most, Plaintiff’s exhibits show that Vifor entities worked cooperatively with the U.S. Defendants to achieve growth in the American market. The exhibits make references, for example, to “Vifor Pharma’s U.S. partner American Regent, Inc.” and the “continued close collaboration between Vifor Pharma and its U.S. partner Luitpold Pharmaceuticals, Inc.” Even accepting Plaintiff’s allegations as true and viewing all factual disputes in her favor, *see Miller Yacht*, 384 F.3d at 97, this submitted proof is a far cry from supporting the allegation that *Vifor Management* purposefully directed its activities *at Pennsylvania*. For the same reasons, Plaintiff has failed to satisfy the second prong, requiring that the litigation “arise out of or relate to” the defendant’s activities in Pennsylvania.

Even if Plaintiff could establish the requisite minimum contacts with Pennsylvania, she must also demonstrate that exercising jurisdiction over Vifor Management would not offend “traditional notions of fair play and substantial justice.” *See Int’l Shoe Co. v. State of Wash.*, 326 U.S. 310, 316 (1945); *see also Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102 (1987). In evaluating the reasonableness of exercising jurisdiction, courts consider (1) the burden on the defendant, (2) the interests of the forum state, (3) the plaintiff’s interest in obtaining relief, and (4) interstate policy interests. *Asahi*, 480 U.S. at 113.

Vifor Management argues that the burden on it is substantial and thus outweighs the other factors. The Supreme Court has recognized the “unique burdens” on foreign defendants being forced to litigate in the United States and stated this “should have significant weight in assessing the reasonableness of stretching the long arm of personal jurisdiction over national borders.”

Asahi, 480 U.S. at 114. Vifor Management is a Swiss company that has no employees, offices, facilities, or any physical presence in Pennsylvania. Vifor Management argues that Swiss blocking statutes and foreign data protection laws would make it costly and burdensome to litigate in this forum. Plaintiff responds that “Vifor is a pharmaceutical colossus” with “United States affiliates, subsidiaries, and partners” and one employee who lives in New Jersey. While this may be so, it does not negate the fact that Vifor Management’s employees and operations are overwhelmingly in Switzerland.

Under these facts, specific jurisdiction does not exist over Vifor Management in Pennsylvania. Plaintiff’s request for jurisdictional discovery is denied.⁶ Defendant’s motion to dismiss shall be granted with prejudice.⁷

An appropriate order follows.

June 11, 2020

BY THE COURT:

/s/ Wendy Beetlestone

WENDY BEETLESTONE, J.

⁶ “Jurisdictional discovery is only appropriate if a plaintiff presents factual allegations that suggest with reasonable particularity the possible existence of the requisite contacts between the party and the forum state,” *inno360, Inc. v. Zakta, LLC*, 50 F. Supp.3d 587, 596-97 (D. Del. 2014) (internal quotations and alterations omitted) (citing *Toys “R” Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003)), and if a plaintiff’s jurisdictional claim is not “clearly frivolous,” *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass’n*, 107 F.3d 1026, 1042 (3d Cir. 1997) (internal quotations and citations omitted). “[C]ourts in this district have denied jurisdictional discovery where the party that bears the burden of establishing jurisdiction failed to establish a ‘threshold prima facie showing’ of personal jurisdiction.” *Parker v. Learn the Skills Corp.*, 2006 WL 759693, at *4 (E.D. Pa. Mar. 23, 2006). Unlike in *Shuker*, 885 F.3d at 780-81, Plaintiff has not made a prima facie showing of personal jurisdiction over Vifor Management. Based on the parties’ submissions and arguments, Plaintiff has failed to show that Vifor Management purposefully availed itself of the Pennsylvania forum.

⁷ Although leave to amend should be freely granted “when justice so requires . . . a court may deny leave to amend when such amendment would be futile.” *Budhun v. Reading Hosp. & Med. Ctr.*, 765 F.3d 245, 259 (3d Cir. 2014) (internal quotations omitted).